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10/597,718	09/14/2006	Hee Kyung Park	117-06	5322
23713 7590 02/18/2010 GREENLEE WINNER AND SULLIVAN P C 4875 PEARL EAST CIRCLE SUITE 200 BOULDER, CO 80301				
EXAMINER				
WHISENANT, ETHAN C				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/597,718

Applicant(s)

PARK ET AL.

Examiner

Ethan Whisenant

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-22 is/are pending in the application.
4a) Of the above claim(s) 16 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 6-10, 12-14 and 17-22 is/are rejected.
7) ☒ Claim(s) 11 and 15 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 04 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

FINAL ACTION

1. The applicant's response (filed 17 FEB 06) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 6-22** is/are pending with Claim 16 withdrawn from consideration. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

35 USC § 112- 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

3. **Claim(s) 7** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite in that it is unclear as to what is meant by "eDNA". The examiner has assumed that this is a typographical error of the term "cDNA". Please clarify.

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35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 102/103

7. Claim(s) 6-10, 12-14, 17-19 is/are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gillibolian et al. [US 2003/0235828].

Claim 6 is drawn to a method for fabricating a microarray said method comprising immobilizing on a support of a microarray a QC probe and a target probe or a spacer base and a QC probe which acts as a target probe, wherein the target probe or the QC probe which acts as a target probe comprise an oligonucleotide having a sequence complementary to a base sequence of a target material and wherein the quality control probe or the quality control probe which acts as a target probe comprise an oligonucleotide labelled at one or more positions with a fluorescent material having a different excitation/emission wavelength from a fluorescent material labelled in the target material.

Gillibolian et al. teach a method of fabricating a microarray which comprises immobilizing a probe or probes on a microarray. In particular, in ¶ [0038] Gillibolian et al. teach immobilizing 1000-25,000 labeled oligonucleotide molecular beacon type probes on an array, also note that Gillibolian et al. teach immobilizing their probes via a spacer (i.e. a spacer base). Any of the probes on the array of Gillibolian et al. could be termed and function as a QC probe. Finally, note that the probes of Gillibolian et al. are labeled at one or more positions with a fluorescent material.

Claim 7 is drawn to an embodiment of the method of Claim 6 wherein the QC probe and the target probe are selected from a defined group which includes oligonucleotide

Gillibolian et al. teach this limitation, see at least for example ¶ [0038].

Claim 8 is drawn to an embodiment of the method of Claim 6 wherein the QC probe and the target probe are simultaneously immobilized on one spot.

Gillibolian et al. inherently teach this limitation. As each oligonucleotide probe is immobilized at one of the spots on the array(s) of Gillibolian et al. both QC probes and the target probes are simultaneously spotted and immobilized. See at least for example ¶ [0038].

Claim 9 is drawn to a microarray having immobilized thereon a spacer base and a QC probe and a target probe or a QC probe which acts as a target probe. The target probe or the QC probe which acts as a target probe have a sequence complementary to a base sequence of a target material. In addition, wherein the quality control probe or the quality control probe which acts as a target probe comprise an oligonucleotide labelled at one or more positions with a fluorescent material having a different excitation/emission wavelength from a fluorescent material labelled in the target material.

Gillibolian et al. teach a microarray which comprises all of the structural limitations recited. In particular, see ¶ [0038] of Gillibolian et al. wherein this author teach immobilizing 1000-25,000 labeled oligonucleotide molecular beacon type probes on an array, also note that Gillibolian et al. teach immobilizing their probes via a spacer (i.e. a spacer base). Any of the probes on the array of Gillibolian et al. could be termed and function as a QC probe. Finally, note that the probes of Gillibolian et al. are labeled at one or more positions with a fluorescent material.

Claim 10 is drawn to an embodiment of the microarray of Claim 9 wherein the QC probe and the target probe are simultaneously immobilized on one spot.

Gillibolian et al. inherently teach this limitation. As each oligonucleide probe is immobilized at one of the spots on the array(s) of Gillibolian et al. both QC probes and the target probes are simultaneously spotted and immobilized. See at least for example ¶ [0038].

Claim 12 is drawn to a method of inspecting the quality of a microarray which comprises using the microarray of Claim 9 to perform identifying an immobilization state of probes and/or hybridization reaction with a target product.

Gillibolian et al. teach using a microarray as set forth in Claim 9 in a hybridization assay. Gillibolian et al. teach using their array to detect particular target nucleic acids in a biological sample. Gillibolian et al. do not teach judging the quality of the microarray based on the hybridization results obtained. However, it was known to judge the quality/success of a given experiment in the hybridization arts by accessing the success or failure of a control. The use of controls is central/fundamental to scientific research. Thus absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to judge the success or failure of the assay practiced by Gillibolian et al. The ordinary artisan would have been motivated to make this modification to the assay practiced by Gillibolian et al. in order to insure that the results obtained are accurate and that the assay was carried out properly.

Claim 13 is drawn to an embodiment of the method of inspecting of Claim 12 wherein the immobilization state of probes is identified by scanning a fluorescent signal before or after a hybridization reaction of the target probe and target probe.

Claim 14 is drawn to an embodiment of the method of inspecting of Claim 12 wherein the hybridization reaction of the target probe and the target product is checked by scanning a fluorescent signal produced by a fluorescent material labeled in the target

product after a hybridization reaction of the target probe and the target product.

Gillibolian et al. inherently teach these limitations for at least the reasons set forth above, see at least for example ¶ [0038].

Claim 17 is drawn to an embodiment of the method of inspecting of Claim 6 wherein the fluorescent label is at one or more positions of the QC probe said position selected from a defined group which includes the 3' end and the 5' end.

Gillibolian et al. teach this limitation, see at least Figure 2.

Claim 18 is drawn to an embodiment of the method of inspecting of Claim 6 wherein a space is further included between the probe sequence and the fluorescent material.

Gillibolian et al. teach this limitation, see at least Figure 2. The arm sequences of the molecular beacon probes comprise a space between the probe sequence (i.e. the sequence of the loop portion) and the fluorescent material.

Claim 18 is drawn to an embodiment of the method of fabricating a microarray of Claim 6 wherein a space is further included between the probe sequence and the fluorescent material.

Gillibolian et al. teach this limitation, see at least Figure 2. The arm sequences of the molecular beacon probes comprise a space between the probe sequence (i.e. the sequence of the loop portion) and the fluorescent material.

Claim 19 is drawn to an embodiment of the method of fabricating a microarray of Claim 6 wherein the fluorescent material is a material selected from a defined group which includes FAM.

Gillibolian et al. teach this limitation, see at least ¶ [0050].

Claim 20 is drawn to an embodiment of the microarray of Claim 9 wherein the fluorescent label is at one or more positions of the QC probe said position selected

from a defined group which includes the 3' end and the 5' end.

Gillibolian et al. teach this limitation, see at least Figure 2.

Claim 21 is drawn to an embodiment of the microarray of Claim 9 wherein a space is further included between the probe sequence and the fluorescent material.

Gillibolian et al. teach this limitation, see at least Figure 2. The arm sequences of the molecular beacon probes comprise a space between the probe sequence (i.e. the sequence of the loop portion) and the fluorescent material.

Claim 22 is drawn to an embodiment of the microarray of Claim 9 wherein wherein the fluorescent material is a material selected from a defined group which includes FAM.

Gillibolian et al. teach this limitation, see at least ¶ [0050].

CLAIM OBJECTIONS

8. **Claim(s) 11 and 15** is /are objected to as being dependent upon a rejected base claim, but would appear to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

9. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new ground(s) of rejection.

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CONCLUSION

10. Claim(s) 6-22 is/are rejected and/or objected to for the reason(s) set forth above.

11. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30 am -5:30 pm EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/
Primary Examiner
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